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| APPLICATION NO.                           | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/533,956                                | 03/22/2006  | Nobuhiko Doumoto     | 052461              | 8069             |
| 38834                                     | 7590        | 11/12/2008           |                     |                  |
| WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP |             |                      | EXAMINER            |                  |
| 1250 CONNECTICUT AVENUE, NW               |             |                      | BADR, HAMID R       |                  |
| SUITE 700                                 |             |                      | ART UNIT            | PAPER NUMBER     |
| WASHINGTON, DC 20036                      |             |                      | 1794                |                  |
|   |             |                      |                     |                  |
|   |             |                      | MAIL DATE           | DELIVERY MODE    |
|   |             |                      | 11/12/2008          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/533,956             | DOUMOTO ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | HAMID R. BADR          | 1794                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-13 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-13 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 04 May 2005 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____ .                                     |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/4/2005</u> .  | 6) <input type="checkbox"/> Other: ____ .                         |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 3 is objected to because of the following informalities: Species name of the genus *Listeria* is required. Appropriate correction is required.

### ***Objection to Abstract***

The abstract of the disclosure is objected to because it consists of two paragraphs. Abstracts should be in one paragraph having a maximum of 150 words. Correction is required. See MPEP 608.01(b).

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the microorganism(s) is/are essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism(s) is/are not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit(s) of the microorganism(s). The specification does not disclose a repeatable process to obtain

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the microorganism(s) and it is not clear from the specification or record that the microorganism(s) is/are readily available to the public.

This rejection may be overcome by establishing that the each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein.

If the depository is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his/her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney over his/her registration number, showing that,

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;

- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,
- (d) the deposit will be replaced if it should ever become inviable.

The specification must also state the date of deposit(s), the number(s) granted the deposit(s) by the depository and the name and address of the depository.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nauth et al. (US 6,242,017; hereinafter R1) in view of JP 11-323328 A (Machine Translation, hereinafter R2) and EP 0640291 (Machine Translation, hereinafter R3).

5. R1 discloses a stabilized meat product comprising nisin containing whey. (Abstract).

6. R1 discloses that by using the nisin containing whey, the growth of Gram positive pathogens including *Listeria monocytogenes* is inhibited. (Col. 3, lines35-38)

7. R1 discloses that a variety of meat products including fish and seafood can be protected against the pathogens. (Col. 3, lines 45-46).

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8. R1 discloses that nisin containing whey may be obtained by cultivation of *Lactococcus lactis* in a dairy liquid such as milk and separating the curd from the whey after the fermentation process by centrifugation or filtration. The resulting whey contains nisin (Col. 6, lines 25-45).

9. R1 teaches that the nisin containing whey will be incorporated into the meat to be protected against pathogens by mixing in a gravy which is cooked at about 74-93C and cooled to about 5C. The meat can be raw or cooked prior to combination with gravy. (Col. 6, lines 46-67). The meat can be lamb, beef, pork, poultry and seafood such as vertebrate fish or an invertebrate shellfish (Col. 7, lines 1-4).

10. R1 is silent regarding the antioxidative properties of the nisin containing whey used in the preservation of fish and shellfish.

11. R2 discloses the antioxidative activity of aminocarbonyl compounds which exist in heat treated dairy products and a method for reinforcing such activities [0007].

12. R2 discloses that the antioxidative property of the aminocarbonyl compounds in the dairy product can be enhanced by inoculating the medium with lactic acid bacteria. [0008].

13. R2 discloses that the amino group containing compound may be milk protein, bovine serum albumin (BSA), soybean protein, wheat protein, egg protein and amino acids such as histidine and arginine. The carbonyl compound may be glucose, fructose, xylose etc. [0010]

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14. R2 teaches the necessary step of heat treatment of the medium after the fermentation. R1 discloses a sterilization process at 100 to 121 C for 7-90 minutes. [0015].

15. R2 disclose inoculating the medium with lactic acid bacteria including *Lactococcus lactis*, *Lactobacillus bulgaricus* et. [0017].

16. R2 disclose that the fermented product can be used as an anti-oxidant as it is or can be diluted and used in foods or drinks [0018].

17. R2 discloses that the anti-oxidant activity is due to proteases produced by the lactic acid bacteria . [0019]. Given that certain peptides are produced through the action of lactic acid bacteria proteases, it is clear that either such peptide or special aminocarbonyl interactions involving these peptides will enhance the anti-oxidative property of these compounds.

18. R2 discloses that the anti-oxidative activity is enhanced by heat sterilization [0026].

19. R2 discloses that the culture solution of the fermented product is high even after removing the bacterial cells by centrifugation. [0037].

20. R1 and R2 are silent regarding the use of *Lactobacillus sake*.

21. R3 discloses that *Lactobacillus sake* can produce bacteriocin which can be used for the preservation of foods. [page 1, paragraph 8]. Therefore, it would have been obvious to one of ordinary skill in the art to use *Lactobacillus sake* in the cultivation medium of R1 and heat sterilize as taught by R2 in order to produce anti-oxidative agent or color tone preserving agent as presently claimed.

22. The presently claimed combination of anti-bacterial and anti-oxidative properties of a cultivation medium in which a lactic acid bacterium has had activity is clearly disclosed by R1 and R2. It is noted that the color characteristic of salmon is astaxanthin which can be preserved due to the anti-oxidant properties as disclosed by R2. Nisin produced by the lactic acid bacteria and as disclosed by R1, will protect the meat against pathogens such as *Listeria monocytogenes*. The co-cultivation of two lactic acid bacteria as presently claimed, will have synergistic and symbiotic effects on the growth, nisin production and proteolysis of the medium components which will ultimately improve the antibacterial and anti-oxidative properties of the cultivation medium as presently claimed.

23. The sterilization of the cultivation medium as presently claimed will destroy any lactic acid bacteria remaining in the separated cultivation medium. It will also enhance the anti-oxidative properties of the cultivation medium as disclosed by R2. It is also obvious that the cultivation medium can be applied to the surface of fish fillet, for instance, by immersion of the meat piece into the cultivation medium as presently claimed.

24. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to prepare nisin-containing cultivation medium with antioxidative properties and apply it to fish and shellfish as taught by R1, R2 and R3. One would do so to protect the fish or shellfish against pathogens and preserve the natural color of a fish such as salmon due to the antioxidative properties of the cultivation medium.

Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in preserving food such as fish.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:00 to 3:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr  
Examiner  
Art Unit 1794

/Callie E. Shosho/  
Supervisory Patent Examiner, Art Unit 1794

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